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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/508,487	03/10/2000	SVEN BERGSTROM	454312-3150	9076

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NEW YORK, NY 10151

EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 07/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/508,487

Applicant(s)

BERGSTROM, SVEN

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25April2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 73-111 is/are pending in the application.
- 4a) Of the above claim(s) 107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 73-106 and 108-111 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 73-111 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. Applicants' Response to Office Action, received 25 April 2002, paper #12, is acknowledged.

Claims 1-72 have been canceled without prejudice. New claims 73-111 have been added.

2. Claims 73-131 are pending. Claim 107 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Claim 107 is drawn to nucleic acid and would have been included with the prior claims directed to nucleic acid.
3. Claims 73-106 and 108-111 are pending and under consideration.

Rejections Moot

4. The rejection of claims 20-32 under 35 U.S.C. 101, is moot in light of the cancellation of the claims.
5. The rejection of claims 50-52, 55-57, 61, 67-69 under 35 U.S.C. 112, first paragraph, is moot in light of the cancellation of the claims.
6. The rejection of claims 20-35, 50-52, 55-57, 59, 61, and 65 under 35 U.S.C. 112, second paragraph, as being indefinite, is moot in light of the cancellation of the claims.
7. The objection to claims 67-70 is moot in light of the cancellation of the claims.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 73-106 and 108-111 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to a polypeptide which exhibits "substantial" reactivity with an polyclonal antibody raised against a second polypeptide which is "derived" from *B. burgdorferi* strain B313.

It is unclear what are the metes and bounds of "substantial" reactivity.

It is unclear what is meant by "derived".

Claims are directed to a polypeptide which is "substantially" absent from various species of *Borrelia*. It is unclear what are the metes and bounds of "substantiall absent".

11. Claims 73-106 and 108-111 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific antibody described in Example 2.2, does not reasonably provide enablement for all polyclonal rabbit antibodies raised against a 13 kDa polypeptide from *B. burgdorferi* strain B313. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - a polypeptide which reacts with a polyclonal rabbit antibody raised against a 13 kDa polypeptide derived from *B. burgdorferi* B313, comprising select amino acid sequence of SEQ ID NO:19.

The state of the prior art for purification of *Borrelia* proteins and production of antibodies against such polypeptides is high, however, the lack of predictability in the art for the claim polypeptide is also high because of the indefinite and open language of the instant claims.

The amount of direction or guidance present - The instant specification is unclear what is meant by a polypeptide "derived" from *Borrelia*. The examples presented are of polypeptides "purified" from *Borrelia*. The open language of the claims, i.e., the second polypeptide which is utilized to produce an antibody "comprises" parts of SEQ ID NO:19. Thus, antibodies produced in response to immunization with this polypeptide may also be directed to the unknown regions of the polypeptide not contained with SEQ ID NO:19. Therefore the identity of the epitope is unknown.

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The presence or absence of working examples - the one example provided by the instant specification is one polyclonal rabbit antiserum raised against purified 13 kDa protein from *B. burgdorferi* strain B313.

The quantity of experimentation necessary to fulfill the scope of the instant claims therefore constitutes merely an invitation to experiment without a reasonable expectation of success except utilizing the one antibody actually produced.

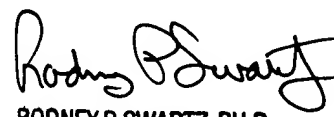
Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., whose telephone number is (703) 308-4244. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (703)308-3909. The facsimile telephone number for the Art Unit Group is (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703)308-0196.


RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

July 15, 2002